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EXAMINER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MANFRED BOHN,
KARL THEODOR KRAEMER, and ASTRID MARKUS

Appeal¹ 2009-000839
Application 10/606,229
Technology Center 1600

Decided:² July 21, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Oral Hearing held June 25, 2009.

² The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is a decision on appeal³ under 35 U.S.C. § 134 from the Examiner's final rejection of claims 14-23 and 26-29. We have jurisdiction under 35 U.S.C. § 6(b).

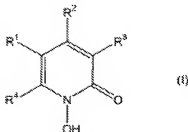
STATEMENT OF THE CASE

The claims are directed to a method of treating seborrheic dermatitis.

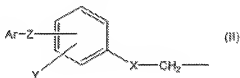
Claim 14 is representative of the claims on appeal, and reads as follows:

14. A method of treating seborrheic dermatitis comprising administering to a human seborrheic dermatitis patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) a sole active component consisting of at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



where R^1 , R^2 , and R^3 , which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

³ This Appeal is related to Appeal No. 2004-0309, decided September 15, 2004.

Z is a single bond, or a linking radical comprising

- (1) O or
- (2) S, or
- (3) -CR₂-, where R is H or (C₁-C₄)-alkyl, or
- (4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:
 - (i) carbon-carbon double bond, and
 - (ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C₁-C₄)-alkyl, or a mixture thereof; and

Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C₁-C₄)-alkyl, trifluoromethyl, and trifluoromethoxy; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; wherein the composition has a pH ranging from about 4.5 to about 6.5; and wherein the composition is a single composition.

The Examiner relies on the following evidence:

Dittmar	US 4,185,106	Jan. 22, 1980
Ramachandran	US 5,834,409	Nov. 10, 1998

H. Hanel et al., "Therapy of seborrheic eczema with an antifungal agent with an antiplogistic effect," 34 Supp 1, *Mycoses*, 91-3 (1991).

Online Medical Dictionary, 27 Sept. 1997.

Appellants rely on the following evidence:

Dr. Mitchell Wortzman Declaration, June 6, 2003.

Gerd Plewig et al., "Chapter 126-Seborrheic Dermatitis," *Dermatology in General Medicine*, 5th Edition, CD-ROM, 1-17 (1999).

Kenneth A. Arndt, "Seborrheic Dermatitis and Dandruff" *Manual of Dermatologic Therapeutics*, Chapter 29, 164-167.

Handbook of Nonprescription Drugs, Chapter 26, *Dermatitis*, American Pharmaceutical Association, 550-552.

Kevin Kriel Declaration, Sept. 20, 2006.

We affirm.

ISSUES

The Examiner concludes that claims 14-23 and 26-29 are rendered obvious by the combination of Dittmar, Hanel, and the Online Medical Dictionary or Ramachandran.

Appellants contend that there is no nexus between Dittmar's treatment of dandruff and Hanel's treatment of seborrheic eczema, and thus there is no reason to combine the references as suggested by the Examiner. Appellants contend further that even if the Examiner has established a prima facie case of obviousness, it has been overcome by evidence of commercial success.

Thus the issues on appeal are:

- (1) Have Appellants demonstrated that the Examiner erred in combining Dittmar with Hanel to arrive at the method of claim 1?
- (2) Have Appellants demonstrated that the Examiner erred in not finding the evidence of commercial success sufficient to overcome any prima facie case of obviousness?

FINDINGS OF FACT

FF1 The present invention is drawn to the “[u]se of 1-hydroxy-2-pyridones for the treatment of seborrheic dermatitis.” (Spec. 1.)

FF2 The Specification notes that “[i]t is known that 1-hydroxy-2-pyridones and their salts exhibit activity against normal dandruff which is characterized by a clinically noninflammatory scaling of the scalp occurring in nearly all people.” (*Id.*)

FF3 According to the Specification, “[s]eborrheic dermatitis is understood as meaning a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites.” (*Id.*)

FF4 The Specification teaches that the “most promising type of treatment of seborrheic dermatitis until now was the topical application of corticosteroid preparations, but more recently topical therapy with antimycotic substances has gained importance.” (*Id.*)

FF5 The Specification teaches further:

While corticosteroid preparations display their activity exclusively via an effect on the inflammatory process, the antimycotic substances such as ketoconazole are active exclusively against the yeast fungi of the strain *Pityrosporum* which is assumed to be the cause of seborrheic dermatitis. The 1-hydroxy-2-pyridones according to the invention, however, combine the properties of both classes of substance in one substance and exhibit both antiinflammatory action and antimycotic activity against *Pityrosporum* strains.

(*Id.*)

FF6 The Examiner rejects claims 14-23 and 26-29 under 35 U.S.C. § 103(a) as being obvious over the combination of Dittmar, Hanel, and the Online Medical Dictionary⁴ (Ans. 4). As Appellants do not argue the claims separately, we focus our analysis on claim 14, and claims 15-23 and 26-29 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

FF7 The Examiner finds that Dittmar teaches “an effective anti-dandruff treatment using a pharmaceutical composition containing 1-hydroxy-pyridones (e.g. ciclopirox (1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone) . . . as active agent.” (*Id.* (citing Dittmar, Abstract and column 2).)

FF8 The Examiner notes that the instant claims differ from the teachings of Dittmar as the instant claims are “directed to a method of treating seborrheic dermatitis.” (Ans. 4.)

FF9 The Examiner finds that Hanel teaches that the “antimycotic agent ciclopiroxolamine (i.e. cic, or 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone) or rilopirox are effectively used to treat seborrheic eczema in human patients.” (Ans. 5.)

FF10 The Examiner finds further that Hanel teaches “the significant therapeutic effectiveness achieved by ciclopirox (cic, hereafter) where strong inhibition of inflammation and infiltration and flakiness has been obtained by cic treatment in the form of a cream in human patients.” (*Id.*)

FF11 The Examiner relies on the Online Medical Dictionary for noting “that seborrheic eczema is an alternative term for seborrheic dermatitis.” (*Id.*)

⁴ We note that while the Examiner cites Ramachandran in the statement of the rejection, it is not discussed in the body of the rejection. We thus do not consider it in reviewing the merits of the rejection.

FF12 The Examiner concludes:

[T]he deficiency of Dittmar is well-remedied and it would have been obvious to one of ordinary skill in the art to select a composition containing 1-hydroxy-2-pyridones (e.g. cic or ciclopirox) as a drug of choice and a surfactant to treat seborrheic dermatitis effectively because the safety and therapeutic efficacy are well proven by the references and the increased selection option increases industrial applicability where the main drawback factors associated with manufacturing antimycotic, antifungal and antibacterial pharmaceutical products are resolved since the toxicities and safety are well proven by the cited references in addition to cost reduction (by avoidance of toxicity, efficacy studies) could benefit the users (patients).

(*Id.*)

FF13 The Examiner concludes further that “one of ordinary skill in the art would have recognized that both Dittmar and Hanel teach the use of the same compound (i.e. ciclopiroxolamine) which may be used to treat similar conditions (i.e. dandruff, as in Dittmar, or seborrheic eczema (dermatitis) as in Hanel).” (*Id.* at 7.)

FF14 The Declaration of Mitchell S. Wortzman states that dandruff and seborrheic dermatitis are separate and distinct conditions (Wortzman Declaration, ¶4).

FF15 The Declaration further states that “[o]ne of ordinary skill in the art would not find it obvious to use a certain composition to treat seborrheic dermatitis, merely because the same composition is used to treat dandruff.” (*Id.* at ¶7.)

FF16 Appendix A to the Wortzman Declaration is a chapter from Dermatology in General Medicine entitled “Seborrheic Dermatitis.”

FF17 Appendix A states good results may be obtained with antifungals, which are usually prepared in the form of a shampoo (Exhibit A, page 10 of 17). Exhibit A also states that “[g]ood results are achieved with topical application of antifungal agents, especially imidazoles.” (*Id.*) The Exhibit notes further that imadazoles such as ciclopiroxolamine may also be effective (*id.*).

FF18 Appendix C is a chapter from the Handbook of Nonprescription Drugs.

FF19 Appendix C notes that the “treatment of seborrheic dermatitis is similar to that of dandruff.” (Appendix C, p. 552, second column.)

FF20 The Declaration of Kevin Kriel states that “Lorprox® Shampoo is a ciclopirox-containing shampoo covered by claims 14, 15, 17, 18, 19, 20, 22, and 23 of this patent application.” (Kriel Declaration, ¶1.)

FF21 The Declaration states that Lorprox® Shampoo is marketed on the basis of its effectiveness, and is sold at a premium price (*id.* at ¶6).

FF22 The Declaration also states that the number of prescriptions for Lorprox® Shampoo grew about 13% from June 2005 to June 2006 (*id.* at ¶8).

PRINCIPLES OF LAW

During examination the PTO must interpret terms in a claim using “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

In *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court rejected a rigid application of a teaching-suggestion-motivation test in the obviousness determination. The Court emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. Thus, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). Further, “[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *KSR*, 550 U.S. at 417. It is proper to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. *See also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

“In determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted). Moreover, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable

solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated technical success, it is likely the product not of innovation but of ordinary skill and common sense.” *KSR*, 550 U.S. at 421.

To be given substantial weight in the determination of obviousness or non-obviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore, the Examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 n.42 (Fed. Cir. 1985). In particular, an Appellant asserting secondary considerations to support its contention of non-obviousness bears the burden of proof of establishing a nexus between the claimed invention and evidence of secondary considerations. For example, in the case of evidence of commercial success, the Federal Circuit has acknowledged that the Appellant bears the burden of establishing a nexus, stating:

In the *ex parte* process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion that the sales constitutes commercial success. *Cf. Ex parte Remark*, 15 USPQ2d 1498, 1503 (Bd. Pat. App. & Int. 1990) (evidentiary routine of shifting burdens in civil proceedings inappropriate in *ex parte* prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

In re Huang, 100 F.3d 135, 139-40 (Fed. Cir. 1996). *See also In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) and *In re Paulsen*, 30 F.3d 1475, 1482

(Fed. Cir. 1994) (Evidence of commercial success of articles not covered by the claims subject to the obviousness rejection was not probative of non-obviousness). Objective evidence of non-obviousness, including commercial success, must be commensurate in scope with the claims. *See In re Tiffin*, 448 F.2d 791, 792 (CCPA 1971) (evidence showing commercial success of thermoplastic foam “cups” used in vending machines was not commensurate in scope with claims directed to thermoplastic foam “containers” broadly).

When the Appellant provides rebuttal evidence, the Board must start anew, and weigh the evidence upon which the earlier conclusion of obviousness was reached against the facts established by the rebuttal evidence to reach a legal conclusion of obviousness or non-obviousness. *See In re Piasecki*, 745 F.2d 1468, 1472-73 (Fed. Cir. 1984) and *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976).

ANALYSIS

Appellants argue that “even if one of ordinary skill in the art did consider seborrheic eczema to be the same condition as SD [seborrheic dermatitis], there is still no nexus between *Dittmar*’s treatment of dandruff and *Hanel*’s treatment of seborrheic eczema.” (App. Br. 10.)

As to *Dittmar*, Appellants argue that *Dittmar* relates only to the treatment of dandruff, and that “[t]here is no teaching whatsoever in *Dittmar* of a method of treating SD or any suggestion that its compositions could be used in the treatment of SD,” and that “in admitting that *Dittmar* does not teach the use of the composition for treating SD, the Examiner

acknowledges that SD and dandruff are in fact different conditions.” (*Id.* at 13.) Hanel, Appellants assert, is relied upon for teaching “that an antimycotic agent such as 1-hydroxy-2-pyridone, for example ciclopirox, was effectively used to treat seborrheic eczema in humans.” (*Id.* at 13.)

According to Appellants, “there is no motivation to combine *Dittmar*, *Hanel*, and the cited ‘medical dictionaries’ as suggested by the Examiner.” (*Id.* at 14.) Appellants contend that “[n]othing in the references cited by the Examiner equates dandruff, as discussed in *Dittmar*, and seborrheic eczema, as discussed in *Hanel*,” and that there is thus “no suggestion or motivation to modify *Dittmar*’s treatment of dandruff for use in treatment of SD.” (*Id.* at 15.) Appellants cite the Declaration of Dr. Mitchell Wortzman, as clearly distinguishing “dandruff from seborrheic dermatitis.” (*Id.*) Appellants thus conclude “because dandruff and seborrheic eczema are different conditions, as clearly shown by this evidence of record, the skilled artisan would not have been motivated to modify or combine the teachings of *Dittmar* relating to dandruff with the teachings of *Hanel* relating to seborrheic eczema.” (*Id.* at 15-16.)

All of Appellants arguments have been considered, but are not convincing. First, claim 14 is drawn to a method of treating a human seborrheic dermatitis patient, which would include treatment of the symptoms of seborrheic dermatitis, as well as the treatment of any patient population.

Dittmar teaches a shampoo comprising a 1-hydroxy-2-pyridone, such as ciclopirox, for the treatment of dandruff. *Hanel* teaches the use of a ciclopirox cream for the treatment of seborrheic eczema, and Appellants

have not presented any evidence to refute the Examiner's evidence and position that seborrheic eczema and seborrheic dermatitis refer to the same condition. Thus, given the need for a treatment for seborrheic dermatitis, and given Hanel's teaching that ciclopirox cream may be used in the treatment of seborrheic eczema, we agree with the Examiner that it would have been obvious to use the shampoo of Dittmar in the treatment of seborrheic dermatitis.

The Wortzman Declaration does not convince us to the otherwise. The Wortzman Declaration is drawn to establishing that dandruff and seborrheic dermatitis are separate and distinct conditions. The Examiner does not find to the otherwise, but relies on Hanel as the bridge between the treatment of dandruff to the treatment of seborrheic dermatitis.

Appellants argue further that the Examiner had at one point in prosecution acknowledged the non-obviousness of independent claims 14, 19, and 26, based in part, on the commercial success of the commercial embodiment of the claimed invention (App. Br. 16-18). According to Appellants, the Examiner then attempted to discount the commercial success as shown in the declaration of Mr. Kevin Kriel, stating that "the commercial success of Loprox® Shampoo were not commensurate in scope with the claims on appeal." (*Id.* at 17.) Appellants cite the MPEP, § 716.03(a), for the proposition that "[i]n order to be commensurate in scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features." (*Id.* at 17-18.) Appellants assert that the commercial success of Stieprox® outside the US and of Loprox® support the

patentability of the claims as both products fall within the scope of the pending claims (*id.* at 18).

As to commercial success, both the Stieprox® shampoo that is marketed outside of the United States, and Appellants' commercial embodiment, Loprox®, each contain the same active ingredient—ciclopirox. Objective evidence of non-obviousness, however, including commercial success, must be commensurate in scope with the claims. The claims encompass a large genus of active ingredients, as well as surfactants, but Appellants have presented evidence of commercial success to only a single product having one species of that large genus. Thus, Appellants' evidence of commercial success is not commensurate in scope with the subject matter of the claims on appeal.

CONCLUSION(S) OF LAW

We therefore conclude that

- (1) Appellants have not demonstrated that the Examiner erred in combining Dittmar with Hanel to arrive at the method of claim 14; and
- (2) Appellants have also not demonstrated that the Examiner erred in not finding the evidence of commercial success sufficient to overcome any *prima facie* case of obviousness.

We thus affirm the rejection of claims 14-23 and 26-29 under 35 U.S.C. § 103(a) as being obvious over the combination of Dittmar, Hanel, and the Online Medical Dictionary.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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